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The goal of this study is to improve the management of pain related to metastatic breast cancer (MBC) through psycho-social intervention. Although clinical guidelines for the treatment of MBC pain have been issued, under-treatment of pain remains a problem. This study builds upon prior research which has identified poor patient-provider communication as a key barrier to adequate cancer pain management. This study is the first application of a pain skills communication intervention to reduce pain and increase quality of life in MBC patients. MBC patients are being randomly assigned to: a pain knowledge and communication skills training or a nutrition education. To determine the effectiveness of the pain and communication skills intervention, patients receiving this treatment will be compared with those receiving nutrition education on standardized measures of pain, psychological adjustment, and quality of life. Patients participate in four interviews: prior to the intervention, post-intervention and at 1 and 3 month follow-ups. To date, twelve patients have been recruited, and two have completed all four interviews. The study results will provide evidence of the efficacy of a pain communication skills intervention in reducing pain andpsychological distress, and increasing quality of life in MBC patients.

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Catherine Dubman 7/6/00

PI - Signature Date

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Introduction

The goal of the proposed study is to improve the management of pain related to metastatic breast cancer through psycho-social intervention. Pain is a common and highly debilitating symptom for persons with metastatic breast cancer. Indeed, 60% to 90%of these patients report experiencing pain that interferes with their mood (makes them depressed, nervous), as well as their ability to sleep, work, and function sexually. Pain makes it difficult for these patients to enjoy life. Although clinical guidelines for the treatment of metastatic breast cancer pain have been recently issued, under-treatment of pain remains a persistent problem. The proposed study builds upon prior research which has identified poor patient-provider communication as being one of the key barriers to adequate cancer pain management. This study is the first application of a pain skills communication intervention to reduce pain and increase quality of life in metastatic breast cancer patients. The proposed research seeks to investigate the impact of a pain communication and skills training intervention created for metastatic breast cancer patients. The pain intervention will have two parts: (1) a one-on-one session with a heath care provider that addresses misconceptions about pain treatment and teaches participants how to provide and elicit information about pain and pain treatment; and (2) completion of a pain diary at prescribed intervals throughout the course of the study participation period. The intervention addresses: (1) participants' misperceptions about pain and pain treatment for those with metastatic breast cancer; (2) how to describe pain in terms of the 5 "L's": Length (or duration), Location (on the body), Like (i.e. what the pain feels like), Loss (i.e. the ways in which the pain has affected their sleeping patterns or ability to carry out daily activities), and Level of pain (i.e., pain intensity); (3) effective participant communication about pain via the use of role-play; and (4) how patients' can question their health care provider about their pain treatment. An ethnically diverse sample of patients will be randomly assigned (i.e. have a 50/50 chance of being assigned) to: a pain knowledge and communication skills training ("experimental condition"); or a nutrition education ("attention placebo"). To determine the effectiveness of the pain and communication skills intervention, the pain, psychological adjustment (i.e. mood), and quality of life (e.g., ability to work, have relationships with others) of metastatic breast cancer patients who receive this treatment will be compared to the patients who receive nutrition education (i.e. control condition). Patients will undergo a series of assessments using standardized measures (of pain, psychological adjustment and quality of life) before and after receiving the pain knowledge and communication skills training or nutrition education. The data will then be entered into a computerized data base and statistical analysis will be performed to investigate difference between the two groups and changes over time. The role of the family member or friend in pain management will also be investigated. The results of the proposed study will provide evidence of the efficacy of a pain communication skills intervention in reducing pain, psychological distress, and increasing quality of life in metastatic breast cancer patient. Information obtained from the proposed research will be used more generally to develop treatment strategies to reduce the pain and suffering of breast cancer patient. The dissemination of information from this study will facilitate the implementation of such an intervention for breast cancer patient in other cancer centers and general medical settings. The proposed study will also extend the existing general knowledge base about patients' participation in the treatment of pain.

Body

The overall goal of this study is to improve pain management for metastatic breast cancer patients by addressing patients' misconceptions about pain treatment and by teaching them how to talk in more descriptive and specific terms about their pain symptoms to their main health care provider (their oncologist). This study examines the impact of a pain and communication skills intervention on the pain, psychological adjustment (i.e., mood), and quality of life (e.g., ability to work, have relationships with others) of metastatic breast cancer patients randomized to this condition as compared to patients who are randomized to, and who receive nutrition education. The primary study hypotheses are that for women with metastatic breast cancer, a pain communications skills intervention will lead to:(1) increased pain management and thus reduce pain; (2) reduced psychological distress; and (3) increased quality of life.

Procedure: The study recruitment for this randomized clinical trial has begun. Women with breast cancer are being recruited from: Mt. Sinai's Oncology Outpatient Clinic and two Mt. Sinai-affiliated private practices; and Elmhurst's Oncology Outpatient Clinic. Women are being interviewed four times on three separate days. The first interview (Interview #1) occurs immediately prior to the participant's regularly scheduled appointment with their oncologist or health care provider who is the main individual responsible for their cancer-related medical care. Participants are assessed on the following: pain (e.g., intensity, degree of relief, degree of interference with daily life and prescribed pain medications), satisfaction with their overall medical care, their current pain management, pain treatment misconceptions and pain communication skills (PTMPCS), quality of life, attitudinal barriers to pain management, distress, perceived level of self-care and psychological well being. The participants' Karnofsky Performance Status (as rated by the nurse /physician/physician's assistant) is also be obtained. Following the interview, the interviewer sends the participant to a separate room where the health educator randomly assigns her to one of the two study arms. Participants then do the following: (1) receive either the 35 minute attention control or experimental intervention condition; (2) upon completion of the session, return to the waiting room area; and (3) see their health care provider for their scheduled appointment. Participants' main health care provider is not informed as to which study arm the participant has been assigned.The second interview occurs after the medical visit (medical visit #1) on the same day as Interview #1. During this interview, participants complete the PTMPCS, and questionnaire items on socio-demographics, medical treatment and history. They also provide information about their main health care provider (e.g. length of time been his/her patient, gender).

The third interview occurs immediately after the participant's next medical visit (medical visit #2) with their health care provider (approximately three to four weeks post-Assessment Time 1). Participants complete the PTMPCS, and questions concerning: degree of perceived involvement in medical care, distress, satisfaction with current medical care, pain level and pain medications currently being taken, quality of life, health care services utilization, self-care self-efficacy, self-care agency-symptom specific, functional status (Karnofsky scale), and quality of life. The fourth interview occurs approximately 12 weeks post-interview #1.

Immediately after medical visits #1, #2, and #3 participant's main cancer health care providers complete a brief (approximately two minute), open-ended questionnaire concerning the participant's: current prescribed pain medications; whether the pain medication regimen has been changed during this visit and if so, in what ways (e.g. same medication but change in dosage level; or, new medication(s) prescribed); whether participant reported having any symptoms (and if so, what types and how many);whether the participant mentioned pain as a symptom, and if so, how the participant described the pain; the number of questions the participant asked and on what topics.

Training Accomplishments To Date: The research staff have been hired and trained in the study assessments, administering informed consent, intervention protocol, and implementation of the control condition. On-going supervision of the staff is provided which includes review of a sample of the audio-taped participant-educator session by DuHamel (see Quality Assurance Checks in grant application).

Research Accomplishments To Date: To date, the study set up procedures have been accomplished including: recruitment strategies have been set up at each site and the measures have been translated into Spanish. The study data base has also been created and recruitment of study participants has begun. Twelve breast cancer patients have been recruited and have begun the study assessments (four participants from Mt. Sinai and eight from Elmhurst). At this time two participants have completed all four assessment times. Unfortunately, two participants have passed away and one withdrew from the study due to illness progression. The remaining seven participants are active study participants. As indicated in the grant proposal, we expect 100 participants to complete the study. As the number of individuals recruited to date (N=12) is to few to conduct analyses, no manuscripts, abstracts or presentations have been prepared.

Conclusion: The study staff has been hired and trained, and the study recruitment for this randomized clinical trial has begun. To date, there are too few subjects to conduct data analyses. After subjects are accrued, assessments conducted, and the results analyzed, these results will provide evidence of the efficacy of a pain communication skills intervention in reducing pain, psychological distress, and increasing quality of life in metastatic breast cancer patients. Information obtained from the proposed research will be used more generally to develop treatment strategies to reduce the pain and suffering of breast cancer patients. The dissemination of information from this study will facilitate the implementation of such interventions for breast cancer patients in other cancer centers and general medical settings. The proposed study will also extend the existing general knowledge base about patients' participation in the treatment of pain.

Reportable Outcomes

As the number of individuals who have been recruited at this time (N=12) is too few to conduct analyses, to date no manuscripts, abstracts or presentations have been prepared.